J Nutr Food Sci 2016, 6:4 (Suppl)
http://dx.doi.org/10.4172/2155-9600.C1.024

Formulation of nutraceuticals and dietary supplements: Formulation and regulatory challenges

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The formulation of pharmaceutical quality dietary supplements that have adequate physical and chemical stability as well as are safe, cost effective and technologically feasible can entail numerous challenges. In contrast to drugs which are usually well defined chemical entities, botanicals are complex ingredients containing multiple chemical components and often several classes of compounds are present in a single product. Many of these compounds are unstable to heat, light, oxygen, alkaline pH and elevated humidity. They may also have poor flow, bulk density and variable particle size distribution. Thus successful development of nutraceuticals requires knowledge of the fundamental aspects of the physical and chemical properties of the various forms of the ingredients, the use of adequate techniques of manufacturing, selection of the right excipient and the addition of suitable manufacturing overages based upon critical stability studies. Regulatory requirements also pose challenges to the development of dietary supplements. Based on the ingredients and the claims, the formula can fit into different categories in different countries. Registration complexity and timing varies greatly by category and country with ever increasing scrutiny. In this oral presentation, I will talk about the formulation of dietary supplements and how it is similar and/or different from pharmaceutical formulations. The formulation of pharmaceutical quality dietary supplements that have adequate physical and chemical stability as well as are safe, cost effective and technologically feasible can entail numerous challenges. In contrast to drugs which are usually well defined chemical entities, botanicals are complex ingredients containing multiple chemical components and often several classes of compounds are present in a single product. Many of these compounds are unstable to heat, light, oxygen, alkaline pH and elevated humidity. They may also have poor flow, bulk density and variable particle size distribution. Thus successful development of nutraceuticals requires knowledge of the fundamental aspects of the physical and chemical properties of the various forms of the ingredients, the use of adequate techniques of manufacturing, selection of the right excipient and the addition of suitable manufacturing overages based upon critical stability studies. Regulatory requirements also pose challenges to the development of dietary supplements. Based on the ingredients and the claims, the formula can fit into different categories in different countries. Registration complexity and timing varies greatly by category and country with ever increasing scrutiny. In this oral presentation, I will talk about the formulation of dietary supplements and how it is similar and/or different from pharmaceutical formulations.

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Microencapsulation of bioactives for functional food development

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The increasing pressure on the food industry to produce healthy food products has, as a result, unveiled the challenge of processing functional ingredients in a way that meets the requirements of the modern day consumer. The major issues limiting the use of functional ingredients without prior processing include vulnerability to oxidative breakdown, limited water or lipid solubility, poor thermal stability and poor taste. Unprocessed, these ingredients such as bioactive compounds are essentially unsuitable for use as food ingredients due to any of the aforementioned reasons. This leads to the application of microencapsulation technology as one of the methods in production of food ingredients for functional food application. By utilizing microencapsulation technology, it is possible to produce functional ingredients with desirable chemical and physical properties. This paper aims to provide an understanding on the application of microencapsulation processes to produce functional ingredients for foods. Microencapsulation of lipophilic bioactive components (LBCs) and the development in the area will be discussed.

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